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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/703,532	11/01/2000	Dean L. Kamen	1062/C39	1972
2101	7590	10/08/2003	EXAMINER	
BROMBERG & SUNSTEIN LLP 125 SUMMER STREET BOSTON, MA 02110-1618			ODLAND, KATHRYN P	
			ART UNIT	PAPER NUMBER
			3743	

DATE MAILED: 10/08/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/703,532

Applicant(s)

KAMEN ET AL.

Examiner

Kathryn Odland

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 November 2000.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 February 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Drawings

1. The drawings are objected to because they are unclear especially figure 9. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.
2. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: element 940. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.
4. Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 recites, "a **head** coupled to the distal end of the shaft, the head having an endoscope port and **at least one fluid port** ... the handle including a gas supply port in fluid communication with the **at least one gas supply port on the head**." However, a gas supply port in on the head has not been recited. Any art rejection is as best understood.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 1-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Newman et al. in US Patent No. 5,954,713.

Regarding claim 1, Newman et al. disclose an endarterectomy surgical instrument having a shaft (such as 30) having proximal and distal ends, as seen in figure 1; a head (10) coupled to the distal end of the shaft, the head having an endoscope port (12) and at least one fluid port (14); a handle (such as 28) coupled to the proximal end of the shaft, the handle including *a gas supply port in fluid communication with the at least one gas port on the head*, as recited in column 3, lines 49-67 and column 4; and a locking mechanism for retaining an endoscope, as recited in column 5, lines 1-14. However, Newman et al. do not explicitly recite a flow valve for metering flow of gas between the gas supply port and the at least one fluid port on the head. On the other hand it would be obvious to one with ordinary skill in the art to modify the invention of Newman et al. to include a flow valve for metering the flow of gas, for it is **necessary** to control the flow of gas and a valve is the well known method to do so.

Regarding claim 2, Newman et al. disclose a saline solution inlet coupled to the handle for coupling a flow of saline solution to the at least one fluid port on the head, as recited in column 5, lines 3-7.

Regarding claim 3, Newman et al. disclose a fluid connection of the handle to the head of the shaft is provided through a first lumen, as recited in column 3, line 49-column 5 and seen in figure 1.

Regarding claim 4, Newman et al. disclose an endoscope (20) for providing optical coupling through a second lumen between the distal and proximal ends of the shaft, as recited in column 4 and seen in figures 1 and 3.

Regarding claim 5, Newman et al. disclose a fluid connection of the handle to the head of that shaft that is provided through a first lumen (14), further having an endoscope (20) for providing optical coupling through a second lumen (12) between the distal and proximal ends of the shaft, as recited in column 4 and seen in figures 1 and 3.

Regarding claim 6, Newman et al. disclose a first lumen that is identical to the second lumen, which appear to be identical in figure 1.

7. Claims 7-11, 13 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Newman et al. in US Patent No. 5,954,713 in view of Matsui et al. in US Patent No. 6,352,503.

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Newman et al. disclose the invention as applied to claims 1-6 above.

Regarding claim 7, Newman et al. do not recite a grasping device having a retracted configuration and a deployable configuration wherein the grasping device extends away from the head in the deployed configuration. On the other hand, Matsui et al. a grasping device (such as 2) having a retracted configuration and a deployable configuration wherein the grasping device extends away from the head in the deployed configuration, as recited in columns 7-8 and seen in figures 1-7. Therefore, it would be obvious to one with ordinary skill in the art to modify the invention of Newman et al. to include a grasping device for the purpose of blockage removal.

Regarding claim 8, the modification of Newman via the teachings of Matsui would yield a deployment control disposed on the handle of the instrument and in mechanical communication with the grasper device.

Regarding claim 9, it would be further obvious to have a grasper device that is a barb.

Regarding claim 10, it would also be obvious to have a grasper device that is a hook.

Regarding claim 11, Matsui teach a deployment control that is a slide, wherein the graspers are slidable into place.

Regarding claim 13, the subject matter has been covered in that stated above.

Regarding claim 14, a method for performing endarterectomy for removing an obstruction from a blood vessel via inserting the endarterectomy surgical instrument of claim 1 through a single incision in a blood vessel; providing fluid through the at least one fluid port of the head for separating intima media layers of the artery surrounding the blockage; grasping the blockage with a grasping device at the distal end of the endarterectomy instrument and removing the blockage through the incision would also be obvious.

8. Claims 7 and 12-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Newman et al. in US Patent No. 5,954,713.

Newman et al. disclose the invention as applied to claim 1.

Regarding claim 7, Newman et al. do not explicitly recite a grasping device having a retracted configuration and a deployed configuration wherein the grasping device extends away from the head in the deployed configuration. On the other hand, Deaton et al. teach a grasping device (such as 100) having a retracted configuration and a deployed configuration wherein the grasping device extends away from the head in the deployed configuration, as recited in columns 5-8 and seen in figures 1-8. Therefore, it would be obvious to one with ordinary skill in the art to modify the invention of Newman et al. to include the grasping device of Deaton et al. for the purpose of blockage removal.

Regarding claim 11, Deaton et al. teach communication between the deployment control and the grasping device that includes a control wire having a first wire end and a second wire end where the first wire is connected to the grasping device and the second end connected to the deployment control, as recited in column 12, for example. Therefore, it would be obvious to further modify the invention of Newman et al. to include a control wire for the purpose of deployment control.

Regarding claim 12, the subject matter is covered in that stated above.

Double Patenting

9. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

10. Claims 1-14 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-18 of copending Application No. 10/161,094. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are merely reworded

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representations for the same subject matter, perhaps slightly more broad in some aspects while slightly more narrow in others.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure are as follows: US Patent No. 6,508,825; US Patent No. 6,436,107; US Patent No. 6,179,851; US Patent No. 6,039,748; US Patent No. 6,036,713; and US Patent No. 5,928,137.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathryn Odland whose telephone number is (703) 306-3454. The examiner can normally be reached on M-F (7:30-5:00) First Friday Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry A Bennett can be reached on (703) 308-0101. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1113.

Henry Bennett
Supervisory Patent Examiner
Group 3700



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